

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of efficacy of risperidone addition to fluoxetine in obsessive compulsive patients

Protocol summary

Summary

To study the efficacy of addition of risperidone to fluoxetine in obsessive compulsive disorder, we will choose 60 subjects among outpatient clients seeking help in our psychiatric clinic who according to DSM-IV-TR meet the criteria for obsessive compulsive disorder and on Yale Brown rating scale (YBOCS) score at least 16. The subjects will be randomly divided into two groups: one group will be treated with fluoxetine-risperidone and the other with fluoxetine -placebo. Each group consists of 30 subjects in whom psychotic disorders, substance abuse and suicidal ideation have been ruled out and age between 18-65 years. The YBOCS questionnaire will be filled for each patient at the beginning of the study and after 6-12 weeks from treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103083010N2**

Registration date: **2011-04-18, 1390/01/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-04-18, 1390/01/29

Registrant information

Name

Faeze Tatari

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 4618

Email address

ftatari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences and Health Services

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-05-22, 1390/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of efficacy of risperidone addition to fluoxetine in obsessive compulsive patients

Public title

The efficacy of combination of risperidone and fluoxetine in obsessive compulsive patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: obsessive compulsive disorder, New case , age>18, age<65, Yale Brown rating scale >16. Exclusion criteria: substance abuse, comorbid of psychotic disorder, suicidal ideation, Yale Brown rating.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Comittee of Kermanshah University of Medical Sciences and Health Services

Street address

Shahid Beheshti Blvd, 2th Building of Kermanshah University

City

Kermanshah

Postal code

6714673159

Approval date

2010-11-09, 1389/08/18

Ethics committee reference number

9881/420/7/پ

Health conditions studied

1

Description of health condition studied

Obsessive-compulsive disorder

ICD-10 code

F42.8

ICD-10 code description

Anxiety disorder

Primary outcomes

1

Description

Response to treatment

Timepoint

Before treatment, 6weeks after treatment , 12weeks after treatment

Method of measurement

Obsessive compulsive qustioner (Y-Bocs)

Secondary outcomes

1

Description

Clinical side effects

Timepoint

6 and 12 weeks after treatment

Method of measurement

According to patients report

Intervention groups

1

Description

Intervention group: risperidone is started at 0.5 mg/d in the first week and then is elevated to 1 mg/d in the second week and is continued until the end of the third month.

Category

Treatment - Drugs

2

Description

Control group: identical to that of risperidone.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital clinic

Full name of responsible person

Dr. Tatari

Street address

Farabi Hospital of Kermanshah

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Farid Najafi

Street address

Shahid Beheshti boulevard

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Farabi Hospital of Kermanshah

Full name of responsible person

Dr. Fahimeh Jahandar Lashaki

Position

Psychiatry Resident

Other areas of specialty/work**Street address**

Ashayer Boulevard, Dolat Abad

City

Kermanshah

Postal code**Phone**

+98 83 1826 1046

Fax**Email**

fh.jahandar@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Faeze Tatari

Position

Psychiatrist

Other areas of specialty/work**Street address**

Ashayer Boulevard, Dolat Abad

City

Kermanshah

Postal code**Phone**

+98 83 1826 1046

Fax**Email**

ftatari@kums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Fahimeh Jahandar Lashaki

Position

Resident of Psychiatry

Other areas of specialty/work**Street address**

Ashayer Boulevard, Dolat Abad

City

Kermanshah

Postal code**Phone**

+98 83 1826 1046

Fax**Email**

fh.jahandar@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty